510K Summary of Safety and Effectiveness
Fx Devices POGO Screw
Oct 10, 2008

1. Sponsor Name
FxDevices
One South Ocean Blvd., Suite 324
Boca Raton, FL 33432

NOV 2 5 2008

2.

Device Name:	POGO Screw
Panel	Orthopaedic
Classification Name	Smooth or Threaded Metallic Bone Fixation Fastener
CFR Number	Class II (per 21 CFR 888.3040)
Product Code	HWC

3. Identification of Predicate or Legally Marketed Device
The POGO Screw is substantially equivalent to the Smith and Nephew Cannulated Screws cleared under K060736 and the Stryker Medical Asnis III cleared under K071092.

4. Device Description
The POGO Screws are comprised of various size cannulated screws for the fixation of bone fractures. The components are manufactured from 316 surgical stainless steel. The screws are available in various sizes from 55mm to 130mm in length. They are provided sterile and also non sterile to be sterilized by the user prior to use.

5. Intended Use
The POGO Screw is indicated for use in the general management of fractures and reconstructive surgery.

6. Comparison of Technological Characteristics
The POGO Screw and the predicate device accomplish the same function of providing compression fixation between a base bone and a bone fragment. Both devices accommodate a range of total lengths within each product design.

7 Performance Testing
Bench testing was conducted to support equivalency

8 Statement of Equivalency
The POGO Screw is substantially equivalent in design, materials, construction and intended use as those of the predicate. Since the POGO Screw is the same in intended use and technological characteristics as the predicate devices, the POGO Screw does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

The test results demonstrate that the POGO Screw is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FxDevices, Inc.
% Mr. Rich Lipschutz
Operations Manager
One South Ocean Blvd., Suite 324
Boca Raton, Florida 33432

NOV 25 2008

Re: K080649
Trade/Device Name: POGO Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 10, 2008
Received: October 16, 2008

Dear Mr. Lipschutz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080649

Device Name:

Indications For Use:

The POGO Screw is indicated for use in the general management of fractures and reconstructive surgery.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080649